Example of Clinical Affairs Job Description

Our company is growing rapidly and is searching for experienced candidates for the position of clinical affairs. To join our growing team, please review the list of responsibilities and qualifications.

Responsibilities for clinical affairs

- Demonstrated in-depth knowledge of medical device development, clinical trial management of Class II and III devices, and understands the application of appropriate FDA, GCP, and ISO Standards to meet regulatory and compliance requirements
- Performs risk management to minimize project risks, while creating and maintaining project documentation
- Frequent international travel to attend quarterly Potential Available Market (PAM) meetings and interface with Switzerland-based staff
- Integrate scientific and clinical knowledge to successfully execute clinical studies in compliance with investigational plans and all applicable regulations, and in line with business goals and objectives
- Monitor and/or interpret results of clinical investigations in preparation for device application and to establish the conditions essential for determining the safety, efficacy, medical usefulness, and marketability of therapy or medical device product
- Leads and directs pre-market clinical affairs activities to ensure completion of all cross functional activities for product development activities
- Develop and prepare key evaluation documents in conjunction with other team members
- Manage US Safety CRAs and Sr
- Represents Safety during inspections of the company
- Develop significant scientific relationships with clinical investigators and research staff

- Bachelor's Degree in a related field (e.g., biological, medical, public health, regulatory science, physical sciences, engineering) is required
- Minimum of 5 years of experience in medical device industry, inclusive of 3 years of experience managing clinical trials in medical device industry for Endoscopy or related business, 2 years managing department objectives, including personnel and cost centers/budgets, and 2 years managing department objectives, including personnel and cost centers/budgets is required
- Possess a University Degree (Bachelor or Master) in a relevant technical, clinical or biomedical field
- Regulatory knowledge in a number of therapeutic areas, orphan drug experience a plus
- 5+ years in an upstream marketing role or product marketing role
- Bilingual abilities a plus (English and French)